Dissertations

Tension-Free Vaginal Tape and Polyacrylamide Hydrogel in Treatment of Female Stress Urinary Incontinence: A Randomized Clinical Trial

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Abstract

Urinary incontinence is a common condition, affecting almost half of adult women at some point of their lives significantly impairing the quality of life (QoL). Stress urinary incontinence (SUI) is the most common urinary incontinence subtype, especially in younger women < 55 years of age. Pelvic floor muscle therapy is the first-line treatment, but surgical interventions are often needed to adequately treat SUI. Midurethral sling surgery, including tension-free vaginal tape (TVT) using polypropylene mesh, has been the gold standard treatment for the past decades. In recent years, however, concerns about long-term complications such as mesh erosion and pain have led to warnings and even in some countries to suspension of mesh use in vaginal surgery. Bulking agents are a minimally invasive alternative to treat SUI, but their efficacy is traditionally considered to decrease over time. Most of previous studies have focused on women suffering from mixed urinary incontinence (MUI) or those who have previous failed anti-incontinence surgery, rather than those with primary SUI. Transurethral polyacrylamide hydrogel (PAHG, Bulkamid□) bulking agent has shown high short-term subjective success rates and good safety profile, but long-term result of this treatment in primary SUI is undefined.

The aim of this randomized noninferiority study was to compare TVT and PAHG in short-term and long-term follow-up (1, 3, and 5 years) regarding patient satisfaction, efficacy and safety. We also studied changes in QoL and sexual function in short-term and midterm follow-up (1 and 3 years). We randomized 223 women requiring operative treatment for primary SUI to receive TVT or PAHG and 212 women received treatment as randomized (TVT n=104 and PAHG n=108). The follow-up visits took place at 3 months, 1 year, and 3 and 5 years after the primary treatment.

The median satisfaction score (visual analogue scale, VAS 0-100) at 5 years was 98 (IQR 86-100) in the TVT group and 90 (IQR 75-99) in the PAHG group. The VAS score of 80 was reached in 89 (92.7 %) women in the TVT group and in 74 (74.7 %) women in the PAHG group (difference 18.0 percentage points, 95% CI 7.7% to 28.0%) and thus, PAHG did not meet the noninferiority criteria set in our study. Any peri- or postoperative complication before crossover between the groups was detected in 42 (43.8%) women in the TVT group and in 22 (22.2 %) women in the PAHG group (difference 21.5 percentage points, 95% CI 8.4 % to 33.8 %) within the 5-year follow-up period. The results were similar throughout the 5-year follow-up.

Incontinence related QoL measured by short forms of urinary distress inventory (UDI-6) and incontinence impact questionnaire (IIQ-7) improved within the 3-year follow-up period from the baseline ($p<0.00$), except for difficulty emptying the bladder and pain/discomfort. At 1 and at 3 years total scores of UDI-6 and IIQ-7 were lower for TVT compared to PAHG ($p<0.00$) indicating better incontinence related QoL. Improvement in sexual function was seen in both groups regarding coital urinary incontinence and fear of coital urinary incontinence restricting sexual activity ($p<0.00$). However, the TVT group showed significantly better results in questions regarding coital urinary incontinence and the physical domain scores of sexual function survey ($p=0.001$) compared to the PAHG group at the 3-year follow-up.

In conclusion, TVT shows better subjective and objective cure rates at 1, 3, and 5 years. Both TVT and PAHG improve QoL and sexual function with better incontinence and health related QoL scores in the TVT group at 3 years. However, complications are more often associated with TVT. As patient satisfaction remained high in both groups throughout the study and the majority of PAHG treated

women considered themselves cured or improved, PAHG provides a safe and durable alternative for treating women with primary SUI. However, only approximately one third of PAHG patients needed only one PAHG treatment and one third of the PAHG patients ended up with a TVT. Since repeated treatments but also complications increase health care costs, cost-effectiveness needs to be further studied. Patients choosing treatment for SUI often have different expectations and acceptability of possible complications. Therefore, appropriate counselling and shared decision-making between the patient and the clinician are essential for ensuring patient satisfaction after treatment.

Mid-urethral sling surgery: Cure rates, complications and sexual function 10 and 20 years post surgery

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Background

Urinary incontinence (UI) impairs women's quality of life, social interactions, and sexuality. Stress urinary incontinence (SUI), characterized by involuntary urine loss during physical exertion, sneezing, or coughing, affects 10-39% of adult women, particularly those aged 25 to 49. The primary cause of SUI is insufficient urethral support, with childbirth being a major risk factor. Mid-urethral sling surgery (MUS) is the standard surgical treatment for SUI due to its high effectiveness, durability, and low complication rates. However, complications such as erosions, persistent pain, dyspareunia, and reduced sexual function are still major concerns following MUS surgery. Research is therefore required to evaluate cure rates, satisfaction and complication rates after MUS, and also sexual function after MUS surgery. Additionally, it is necessary to conduct further evaluations to determine if the position of the sling in relation to anatomical structures affects the outcomes after MUS surgery.

Aims

The overall aim of the thesis was to gain better knowledge about long-term rates of cure and complications after MUS surgery for stress urinary incontinence (SUI). Specific aims:

Study I: Evaluate the cure, satisfaction and complication rates 10-20 years after MUS surgery.

Study II: Assess sexual function 10-20 years post-MUS surgery.

Study III: Explore associations between sling location, cure rates and complications.

Methods

The Norwegian Female Incontinence Registry identified women who had MUS surgery 10 and 20 years ago. Validated questionnaires were used assessing urinary symptoms and sexual function. Clinical examination included a stress test, erosion check, urodynamics and transperineal ultrasound. Studies I and II were retrospective cohort studies, and study III was a cross-sectional study.

Results

The main findings of the three studies were high subjective (59-68%) and objective cure (93-100%) rates, along with high satisfaction (76-89%). Complication rates were low. Prevalence of persisting pain after MUS was 2.7-4.7%. Women reported reduced leakage during intercourse post-MUS (decrease from 30% to 6%), and pain following MUS did not impact sexual activity. The distance between the sling and the symphysis was not correlated with post-MUS surgery cure rates, voiding difficulties, or persistent pain. Urgency urinary incontinence (UUI) and urinary tract infection (UTI) showed a slight association with a shorter distance between the symphysis and the sling ($p<0.05$).

Conclusion

The overall conclusion of the thesis is that MUS surgery has high subjective and objective cure rates and low risk of long-term complications 10 and 20 years after MUS surgery and does not impact sexual function negatively. Sling location does not correlate with cure rates and complications such as pain and voiding difficulties, however a shorter distance between the sling and symphysis was correlated with UUI and UTI.

Intravesical onabotulinumtoxinA treatment in women with overactive bladder: Optimization of anesthesia and assessment of adverse effects

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Intravesical onabotulinumtoxinA (BTX-A) injections are a well-established third-line treatment for overactive bladder (OAB) syndrome with well-documented efficacy. The overall aim of this PhD thesis was to contribute evidence to the field by optimizing the anesthetic protocol for BTX-A treatment in an outpatient clinic setting and to identify risk factors for adverse events. Local anesthetic approaches for intravesical BTX-A treatments have not been thoroughly investigated, and no standardized anesthetic protocol currently exists. Alkalinized lidocaine has been evaluated with mixed results and has not been tested against placebo. In Study I, we conducted a single-center, randomized, double-blind, placebo-controlled crossover trial to evaluate the effect of intravesical alkalinized lidocaine solution on pain during BTX-A injections. Additionally, procedure-related adverse effects and patient satisfaction with the BTX-A treatment were assessed. We enrolled 50 patients, of whom 41 were eligible for per-protocol analyses. Intravesical alkalinized lidocaine demonstrated a significant reduction in mean visual analog scale (VAS) score, with nearly a 50% reduction compared with placebo ($P < 0.0001$). Adverse events and patient satisfaction did not significantly differ between the alkalinized lidocaine and placebo treatments ($P = 0.825$, $P = 0.138$).

No established guidelines for managing antithrombotic therapy regarding preoperative interruption and postoperative resumption in patients undergoing BTX-A treatments are available. In a single-center retrospective, consecutive cohort study (Study II and Study III), we evaluated 400 women and found that the bleeding risk after BTX-A injections is low, overall and among women on antithrombotic therapy. Based on these findings, we suggest BTX-A treatments be classified as low-risk surgical procedures and to continue antithrombotic therapy perioperatively.

A common adverse effect of BTX-A treatment includes urinary retention, which may necessitate clean intermittent catheterization (CIC). Identification of predictive factors for CIC is of clinical interest, as it may improve patient selection and referral practices and enhance counseling. Study III aimed to evaluate the CIC rate following the first BTX-A treatment and to investigate factors predictive of initiating CIC. Among 397 eligible women, we found a CIC rate of 8.6% following the first BTX-A treatment. Women with a history of anterior colporrhaphy had almost four times the risk of undergoing CIC, while women with urgency urinary incontinence had a lower risk of initiating CIC. We found an association between increased maximum cystometric capacity in urodynamic studies and the risk of CIC. Elevated bladder capacity and the absence of urinary incontinence episodes in pretreatment bladder diaries predicted CIC, consistent with risk factors identified by urodynamic studies.

Pelvic floor trauma after childbirth – Risk factors, surgical treatment, and prevention

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Background

As women live longer, the long-term effects of childbirth may negatively affect their quality of life and professional careers.

Aim

The overall objective of this thesis was to examine how childbirth-related factors, such as delivery mode, number of births, and infant birth weight, affect long-term pelvic floor health in mothers, with a focus on the risks of pelvic floor disorders, surgical interventions, and the prevention of obstetric anal sphincter injury (OASI).

Material and methods

Papers I and II analysed cohorts of women from the Swedish National Quality Register of Gynecological Surgery who underwent prolapse or incontinence surgery. National birth registers were used in Papers I, III and IV to identify women with a first and second vaginal delivery.

Results

In Paper I, pregnancies per se were not associated with an increased risk of surgery for pelvic organ prolapse or urinary incontinence compared with nulliparous women. Vaginal delivery increased the risk of surgery for pelvic organ prolapse or urinary incontinence while cesarean delivery alone preserved long-term pelvic floor support, similar to that of nulliparous women. Paper II: Despite lower cure rates with increasing age and morbidity, most women were satisfied with mid-urethral sling surgery if incontinence episodes decreased. Women with severe incontinence were more likely to improve and report satisfaction. In Paper III, higher infant birthweight reduced the rate of spontaneous vaginal delivery (80.4% to 44.9%) and increased acute cesarean rates (8.3% to 41.6%). Delivery experience declined with higher birthweight, mirroring complication patterns. In Paper IV, incorporating infant biometrics and intrapartum factors improved OASI risk prediction and informed clinical decision-making through an online calculator.

Conclusion

Vaginal delivery increases pelvic floor surgery risk, whereas cesarean delivery is protective. Despite lower cure rates with age and morbidity, most women were satisfied with sling surgery if incontinence symptoms improved. Accurate infant birthweight assessment is crucial for preventing birth trauma and enabling personalised obstetric care.

Keywords

Delivery, vaginal; cesarean section; vaginal birth after cesarean; pelvic floor disorders; birth weight, birth injury; maternal morbidity; obstetric anal sphincter injuries, Probability, Bayes theorem.

Second-degree perineal tears - Classification, risk factors, and consequences

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During vaginal childbirth, the pelvic floor is exposed to tremendous strain. Consequently, most women will experience some degree of tearing of the tissue between the vagina and anus (the perineum). Perineal tears are classified as first- to fourth-degree tears, depending on which- and to what extent anatomical structures are involved. In recent years, significant strides have been made in understanding perineal tears, with the majority of research focusing on tears affecting the anal sphincter muscles (third- and fourth-degree tears). Less focus has been directed towards the most common perineal tear category: second-degree tears, which are presumed to hold little clinical importance.

Second-degree tears are defined as tears affecting perineal muscles, but not the anal sphincter complex. However, second-degree tears vary widely in size, from minuscule perineal muscle damage to larger tissue trauma affecting several muscles and fascia. As the perineal structures, including the perineal body, have important functions in maintaining pelvic floor health, there is reason to believe that larger second-degree tears may be associated with more pelvic floor symptoms compared to lesser forms. To account for the varying degree of tissue trauma within the second-degree category, a sub-classification system for second-degree tears was introduced in the delivery ward of the study hospital for this project. This thesis addresses the large variation in size within the second-degree tear category, including their occurrence, risk factors, and possible consequences.

Paper I

Findings from an inter-rater agreement study assessing agreement between midwives classifying perineal tears using two classification systems. We found good to very good inter-rater agreement between midwives using both classification systems, and the detailed classification system was easy to introduce to a large staff.

Paper II and Paper III

Derived from the “Perineumstudy”, a longitudinal prospective cohort study (1087 women) followed for 12 months after birth. Occurrence among vaginal births without episiotomy: 2A: 19.1%, 2B: 9.8%, 2C: 6.6%. Risk factors and symptom development were analyzed up to 12 months postpartum. While differences in size within the second-degree tear category did not explain differences in pelvic floor symptoms, symptoms did not return to pregnancy levels within the first year postpartum.

Clinical evaluation after incontinence surgery and dehisced perineal tears: effects on women ´s pelvic floor health

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Introduction

The prevalence of symptoms resulting from pelvic floor dysfunction are high and urinary incontinence in particular is a burden for the individual as well as for society. Stress urinary incontinence (SUI), which is the most common type of incontinence in women, has since the late 1990s been treated with mid-urethral slings (MUS). Rising concern about risks, complications, and long-term outcome have guided research in this direction. With obesity emerging as a growing global health issue, a known risk factor for urinary incontinence, alongside the aging population in many countries, the need for a clear rationale for treating various types of urinary incontinence is evident. Additionally, the awareness of consequences of a dehisced perineal tear after childbirth has increased. The need for evidence-based best clinical practices is essential to prevent more women from experiencing pelvic floor dysfunction.

The aims of this thesis were to evaluate dyspareunia and pelvic pain following MUS surgery, to investigate the impact of BMI on long-term outcome after MUS surgery, and to compare these findings with a control group of women who had not undergone the procedure. Another objective was to explore optimal treatment strategies for dehisced second-degree perineal tears after childbirth.

Methods and results

Studies I, II, and III were registry-based investigations that included all women who underwent MUS surgery in Sweden and were registered in the Swedish National Quality Register of Gynecological Surgery (GynOp) between 2006 and 2010. In total 2421 women were analysed, 1562 women after retropubic MUS and 859 women after transobturator MUS. In study I dyspareunia, pelvic pain and sexual function, assessed by PISQ-12 were compared between the two surgical techniques, no differences were found. Study II investigated the impact of BMI at the time of MUS surgery on long-term outcomes, specifically focusing on subjective SUI. A higher BMI was significantly associated with lower cure rates both one year and ten years postoperatively. In study III a reference group was added to the GynOp cohort. The comparison of pelvic pain and lower urinary tract symptoms (LUTS) revealed that women aged 50 years or older who had undergone MUS surgery reported significantly more pelvic pain and LUTS than women who had never received a MUS.

Study IV

A multicentre randomised controlled trial examined treatment of dehisced second-degree perineal tears. Early resuturing was compared to conventional conservative management with secondary healing. Healing was significantly faster in the resuturing group, with better psychological well-being at first follow-up.

Conclusions

Dyspareunia, pelvic pain, and sexual function after MUS surgery do not differ between retropubic and transobturator MUS techniques.

An elevated BMI at the time of MUS surgery is associated with a lower cure rate.

Pelvic pain and LUTS appear to be more prevalent in women over the age of 50 who have undergone MUS surgery at least ten years earlier.

In the treatment of dehisced second-degree perineal tears, early resuturing appears to be more effective than conservative management without negatively affecting pain, breastfeeding, or psychological well-being.

https://openarchive.ki.se/articles/thesis/Clinical_evaluation_after_incontinence_surgery_and_dehisced file=58723126
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Pelvic floor symptoms in women undergoing pelvic organ prolapse surgery

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Abstract

One in eight Finnish women undergoes pelvic organ prolapse surgery in her lifetime, primarily due to vaginal bulging. Bladder and bowel symptoms are also common, but the extent to which they result from the anatomical defect of prolapse remains unclear, leading to diverse management approaches.

This doctoral thesis investigates the association between prolapse and overactive bladder, stress urinary incontinence, and anorectal symptoms and it provides tools for gauging the impact of prolapse surgery. Nearly 3,000 prolapse patients were observed for two years postoperatively. The Pelvic Floor Distress Inventory-20 (PFDI-20) was used as the outcome measure.

Overactive bladder symptoms and their postoperative improvement were more pronounced in anterior and apical prolapse than in the posterior compartment. The preoperative degree or compartment of prolapse minimally influenced the stress urinary incontinence status or its postoperative changes. For half of the women, pre-existing stress incontinence improved or resolved postoperatively; bothersome de novo symptoms were rare. Severe preoperative symptoms predicted persistent stress incontinence, and older age was a risk factor for de novo symptoms. Obstructed defecation correlated with the posterior vaginal wall stage, and a greater improvement was noted after posterior compartment surgery than after corrections in other compartments.

Minimal important difference and patient acceptable symptom state estimates were established to interpret changes in the PFDI-20 and its subscale, the Pelvic Organ Prolapse Distress Inventory (POPDI-6). Mean differences of 24 points in the PFDI-20 score and 11 points in the POPDI-6 score denote clinically meaningful improvements. Postoperative PFDI-20 scores ≤ 60 and POPDI-6 scores ≤ 17 indicate acceptable symptom states after surgery.

These findings advance our understanding of pelvic organ prolapse and guide realistic treatment expectations. Overactive bladder symptoms frequently improve after prolapse surgery, particularly following anterior or apical compartment procedures. For many patients, prolapse surgery is the only procedure needed to address stress incontinence. Women with obstructed defecation can anticipate improvements after posterior vaginal wall prolapse correction. However, residual bladder and bowel symptoms remain prevalent, likely due to these symptoms' multifaceted nature.

Keywords: pelvic organ prolapse, pelvic organ prolapse surgery, pelvic floor, overactive bladder, stress urinary incontinence, obstructed defecation, anal incontinence, minimal important difference, patient acceptable symptom state

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